K070389

p. 1/2

BIOMET

510(k) Summary

AUG - 9 2007

Preparation Date: February 8, 2007

Applicant/Sponsor: Biomet Sports Medicine, Inc. (formerly known as Arthrotek, Inc.)

Contact Person: Susan Alexander

Proprietary Name: PEEK Knotless Anchors

Common Name: Soft tissue anchor

Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR §888.3040), HWC

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

• ALLthread™ PEEK Suture Anchors	K060693	Arthrotek, Inc.
• Resorbable Interference Screw	K041274	Arthrotek, Inc.
• Soft Tissue Screw and Washer	K012572	Arthrotek, Inc.

Device Description: The PEEK Knotless Anchors are soft tissue anchors available in four diameters and comprised of PEEK-Optima® polymer.

Indications for Use:
Indications for the PEEK Knotless Anchors include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications are as follows:

Shoulder: Bankart Repair; SLAP Repair; Acromio-clavicular Separation; Rotator Cuff Repair; Capsule Repair or Capsulolabral Reconstruction; Biceps Tenodesis; and Deltoid Repair

Wrist/Hand: Scapholunate Ligament Reconstruction and Ulnar/Radial Collateral Ligament Reconstruction

Ankle/Foot: Lateral Stabilization; Medial Stabilization; Achilles Tendon Repair/Reconstruction; Hallux Valgus Reconstruction; and Mid and Forefoot Reconstruction

Elbow: Ulnar or Radial Collateral Ligament Reconstruction; Biceps Tendon Reconstruction; and Lateral Epicondylitis Repair

Knee: Extra-capsular Repair; Medial Collateral Ligament Repair; Lateral Collateral Ligament Repair; Posterior Oblique Ligament Repair; Joint Capsule Closure; Iliotibial Band Tenodesis; Patellar Realignment and Repair; Patellar Ligament/Tendon Repair; and Vastus Medialis Obliquus (VMO) Muscle Advancement

The PEEK Knotless Anchors are single-use devices.

Summary of Technologies: The technological characteristics (material, design, sizing, indications) of the PEEK Knotless Anchors are similar or identical to the predicate devices.

MAILING ADDRESS
P.O. Box 587
Warsaw, IN 46581-0587

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE
574.267.6639

FAX
574.267.8137

E-MAIL
biomet@biomet.com

K070389

p. 2/2

510(k) Summary
510(k) Notification: PEEK Knotless Anchors
Biomet Sports Medicine, Inc.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the devices were functional within their intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Sports Medicine, Inc.
% Ms. Susan Alexander
Regulatory Specialist
Biomet Manufacturing Corp.
P.O. Box 587
Warsaw, Indiana 46581-0587

AUG - 9 2007

Re: K070389
Trade/Device Name: PEEK Knotless Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 4, 2007
Received: June 5, 2007

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or at Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070389

Indications for Use

510(k) Number (if known):_____

Device Name: PEEK Knotless Anchors

Indications For Use:

Indications for the PEEK Knotless Anchors include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications are as follows:

Shoulder: Bankart Repair; SLAP Repair; Acromio-clavicular Separation; Rotator Cuff Repair; Capsule Repair or Capsulolabral Reconstruction; Biceps Tenodesis; and Deltoid Repair

Wrist/Hand: Scapholunate Ligament Reconstruction and Ulnar/Radial Collateral Ligament Reconstruction

Ankle/Foot: Lateral Stabilization; Medial Stabilization; Achilles Tendon Repair/Reconstruction; Hallux Valgus Reconstruction; and Mid and Forefoot Reconstruction

Elbow: Ulnar or Radial Collateral Ligament Reconstruction; Biceps Tendon Reconstruction; and Lateral Epicondylitis Repair

Knee: Extra-capsular Repair; Medial Collateral Ligament Repair; Lateral Collateral Ligament Repair; Posterior Oblique Ligament Repair; Joint Capsule Closure; Iliotibial Band Tenodesis; Patellar Realignment and Repair; Patellar Ligament/Tendon Repair; and Vastus Medialis Obliquus (VMO) Muscle Advancement

The PEEK Knotless Anchors are single-use devices.

Prescription Use ___X___ AND/OR Over-The-Counter Use ___NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number 4-1 K070389